MEMORANDUM

To: Mark Brown, Ph.D.

From: Edmund A.C. Crouch, Ph.D. and Laura C. Green, Ph.D., D.A.B.T.

Subject: Updates to our June 1, 2001 report, *A Quantitative Health Risk Assessment for the Kalamazoo River PCB Site*

Date: September 10, 2002

We write to update our June 1, 2001 report, *A Quantitative Health Risk Assessment for the Kalamazoo River PCB Site,* in three ways.

First, we correct typographic errors.

Second, we take into account recent measurements of PCBs in sediments and soils in and near the former impoundments (reported in Weston, 2002).

Third, we restrict the reporting of the probabilistic risk assessment (PRA) by ignoring the uncertainties and variabilities in toxicity values for PCBs, and using instead single, upper-bound, fixed values.[1] As you may know, current U.S. EPA policy allows for probabilistic treatment of uncertainties and variabilities in toxicity values for ecologic risk assessment, but discourages such treatment for human health risk assessment.[2] U.S. EPA's PRA Workgroup, however, continues to develop and assess methods for incorporating such uncertainties and variabilities, and might well agree, if petitioned, to provide technical peer review for this important aspect of our June 1, 2001 analysis.

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[1] This update is designed to be read in conjunction with our June 1, 2001 report — there are extensive references to sections in that report. Section U.3 is analogous to Section 6.10 of our June 1, 2001 report, but omits all reference to the toxicity uncertainties and variabilities.

[2] *Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment.* EPA 540-R-02-002. OSWER 9285.7-45. December 2001. PB2002 963302 http://www.epa.gov/superfund/programs/risk/rags3a/].

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U.1 Errata

- Page Summary-7, 3rd to last line on page:

Replace "but the probability any cancers" with "but the probability of any cancers"

- Page 8-2, 2nd to last line

Replace the line "2.2, with an expected value of 1.574%. Thus, it is highly likely that no cancer will ever occur in" with "2.2, with an expected value of 1.5. Thus, it is highly (computed value 74%) likely that no cancer will ever occur in"

- Page 8-7, 3rd line

Replace µg/kg-d with µg/kg-day.

- Figures with captions including the string "ug/kg-day"

This string should read "µg/kg-day"

U.2 Incorporating recent measurements of PCBs in sediments and soils

U.2.1 Recent soil sampling

In May 2001, the U.S. Environmental Protection Agency (U.S. EPA) and Roy F. Weston Inc. (Weston) initiated an assessment of PCB contamination of the sediments in, and the soils surrounding, a portion of the Kalamazoo River (Weston, 2002). The purpose of the program was to provide more accurate data than had been previously available to define and guide remediation and sediment removal efforts. Soil and sediment samples were collected between the Main Street bridge in Plainwell and the downstream Otsego City dam in Otsego (Allegan County, Michigan). This 3.6 mile section of the river is divided roughly in half by the Plainwell dam. The two reaches separated by the dam are quite different with respect to their current and historical conditions.

The Plainwell dam was a former hydroelectric facility which had a head of 13 feet, and the impoundment behind the dam is reported to have been at an elevation of 712 feet. In the early 1970s the dam was drawn down to its sill level; in 1987, the MDNR removed the dam down to its sill (Weston, 2002). The section of the river (reach 1) between the Main Street bridge in Plainwell and the Plainwell dam has a single channel, and a relatively narrow floodplain. Portions of the former Plainwell dam impoundment that are now exposed above the existing water line are covered with historically deposited sediments, and have since revegetated (Blasland & Bouck, 1992b). Some of the soils in this area contain visible grey clay-like deposits (Weston, 2002).

The downstream portion of the river between the Plainwell dam and the Otsego City dam (reach 2) historically had an elevation of approximately 699 feet (USGS, 1973). The river here has multiple (possibly shifting) channels and a more extensive flood plain (Weston, 2002). The area covered by the sampling contains permanently flooded wetlands with unconsolidated bottoms (Weston, 2002), and the area up to 700 feet elevation is shown on the USGS map as a marsh or swamp. The Otsego City dam is close to its historical level — it was drawn down by two to three feet by removal of stop logs in 1991 — so the exposed soils surrounding the river in this reach do not contain so much deposited paper waste as those in reach 1.

The sampling program conducted by the U.S. EPA and Weston had two Phases. The first Phase included sediment and soil sampling on a 300 foot grid pattern and from eight river transects in reach 1, and on a 500 foot grid and from five river transects in reach 2. The second Phase included sampling in radial grids or clusters around eight of the locations sampled in Phase 1. Sediment samples (collected below permanently flooded locations) and soil samples (taken from non-flooded locations) were collected at depth intervals ranging from the sediment-water interface or the soil surface down to the deepest depth possible until native soil was reached or the sampling equipment encountered refusal.

In this update we examine the data collected by the U.S. EPA and Weston and compare them with the data previously collected in the soils of the former Plainwell impoundment. The object of the comparison is to evaluate whether the new data indicate a need to change any conclusions of our previous screening evaluation of the potential risks to human health that might result from exposure to PCB contaminated soils around the Kalamazoo River, and in particular in the former impoundments. The major soil exposures examined for these locations corresponded to contact with surface soil, so we primarily examine the data for surface soil samples taken in the Plainwell impoundment (within reach 1).

The PCB mass fraction (μg/kg) of each sample was determined by analysis and reported as Aroclors 1016, 1221, 1232, 1242, 1248, 1254, and 1260. Aroclors 1016, 1221, 1232, and 1248 were reported as not detected in any of the surface soil samples. Aroclor concentrations were treated as previously detailed in this report — duplicate samples were averaged, and when a point estimate was needed, non-detects were treated as present at ½ the detection limit. As before, Aroclors 1221 and 1232 were treated as not present (concentrations assumed to be zero), since they have never been reported as present in any sample in any medium.

Our previous risk assessment included exposed surface soil data from areas that had been within the former Plainwell impoundment. In order to compare the recent PCB surface soil concentrations from reach 1 (upstream of the Plainwell dam) with those that were included in our previous assessment of the same area, it was necessary to evaluate whether each of the recent sample locations were within the former impoundment area. Because the elevations for the recent sample locations were not available, it was necessary to create a map of the sample locations that could be compared both with USGS map elevations, and with previous maps of the former impoundment. The sampling locations given in the report by the U.S. EPA and Weston are based on the US State Plane grid: Michigan South 2113, NAD 1983, US Survey feet. These

were converted to the UTM coordinate grid: UTM zone 16 NAD27, meters using the U.S. Army Corps of Engineers software Corpscon (USACE, 2001). This allowed the sample locations and data to be plotted and laid over the U.S. Geological Survey 7.5 minute map for the region (USGS, 1973). The sample locations were also compared with a map of the former Plainwell impoundment (BBL, 1994) that includes a contour interval at elevation 712 feet to show the extent of the former impoundment (we previously noted that the demarcation lies between 712.25 and 713.98 feet, based on the evidence from previous samples). The physical descriptions of the samples (Weston, 2002) were also examined to establish which samples were from locations within the former Plainwell impoundment. Generally those samples from lower elevations that had been within the impoundment are described as grey silty clay, while those from higher elevations are brown and sandy. Last, the PCB concentration levels were checked to determine whether the samples were from within the former impoundment.

U.2.2 Soil samples within the former Plainwell impoundment

Of the 38 surface soil samples from upstream of the Plainwell dam, 6 were from locations with elevations indicated to be above 712 feet from available maps (locations 4, 7, 13, 19, 36, and 48). These samples were generally described as being brown and sandy (there was no physical description for sample 7). Three of these samples (4, 13, and 36) had no detectable PCB contamination; the other three had low levels of PCBs detected — the sum of the detected concentrations was less than 0.03 mg/kg, and the total PCB concentration was less than 0.343 mg/kg (assuming the undetected Aroclors to be present at ½ the detection limit). The map location for sample 18 was very close to the 712 feet elevation contour. It was described as grey silty clay, but the only Aroclor that was detected was 1260 at a very low level of 0.0069 mg/kg. PCB concentrations for all seven of these samples (locations 4, 7, 13, 18, 19, 36, and 48) were excluded to ensure comparability with previous data from the former impoundment soils (see Section 5.1).

Eight locations in Phase 1 were selected as center points for Phase 2 radial sampling grids, four of them centered on soil samples (as opposed to underwater sediment samples); three of the four soil samples were in reach 1 of the river where locations may be within the area of the former Plainwell impoundment, and the other grid was in reach 2, outside of the former impoundment. The four soil-sample grids in Phase 2 were centered around locations SL015 (Grid 1), SL029 (Grid2), and SL012 (Grid 6) in reach 1, and around SL053 (Grid 4) in reach 2. The number of samples, their location, and their type, is given in Table U.1.

Table U.1 Numbers of samples in the Phase 2 grids			
Location	Total surface samples	Samples taken in soil	Samples within the former Plainwell impoundment
SL012	28	28	26
SL015	33	33	33
SL029	33	33	32
SL053	36	32	0
SD004	35	0	0
SD030	35	15	0
SD036	38	0	0
SD045	25	0	0

Comparing the sample locations for the three grids in reach 1 with the USGS map and the map of the former Plainwell impoundment (BBL, 1994), only 2 samples from grid 6 (SL012-14 and SL012-21), and 1 sample from grid 2 (SL029-33) appear likely to be from outside the area of the former impoundment. The sample from grid 2 contained no detectable PCBs and the two samples from grid 6 had detectable Aroclor concentrations lower than 0.02 mg/kg, and total PCBs less than 0.08 mg/kg (counting non-detects at ½ the detection limit). Data for these three samples were excluded from the calculations used to compare the recent analyses with those from the previous risk assessment, to ensure comparability (see Section 5.1).

The distributions of PCB concentrations in surface soil samples within the former Plainwell impoundment were compared in various ways between the recent samples (Phase 1, SL029, SL015, and SL012) and the formerly available samples (Section 5.1 — called "Transect" samples in this update). Figure U.1 shows probability plots [3] for the former Transect samples, and for more recent sets of samples, and various statistics are given in Table U.2. Visually, there is little difference between the distributions for the Transect, Phase 1, and SL029 samples, and

[3] Figures U.1 and U.2 plot the logarithm of the mass fraction measured in the samples against a transform of their rank order. The transform is chosen so that a lognormal distribution shows as a straight line on this plot — it is the inverse normal of $(i-3/8)/(n+1/4)$ for the concentration measurement with rank i of n total samples. This value is a close approximation for the expected location of this i^{th} rank measurement if the distribution is lognormal (Cunnane, 1978). Completely non-detect samples would have lower bound estimates extending to infinity on the left. See Section 5.1 for similar plots of PCB mass fractions measured in the other former impoundments.

the SL012 and SL015 sample sets appear distinct. The Transect, Phase 1, SL029, and SL012 distributions are consistent with being lognormal, but the SL015 distribution is not.

Table U.2 Characteristics of samples in the former Plainwell impoundment

Sample set name	Arithmetic		Base 10 logarithm of mg/kg		Number of samples
	Mean (mg/kg)	Standard Deviation (mg/kg)	Mean	Standard Deviation	
Transect	17.6	22.2	0.92	0.57	30
Phase 1	17.7	22.1	0.81	0.72	31
SL029	11.1	12.0	0.79	0.52	32
SL012	21.4	17.0	1.18	0.40	26
SL015	34.9	31.8	1.18	0.80	33

Various statistical tests (see spreadsheet Plainwell.wb3, Section U.5) demonstrate some difference between the distributions, but the arithmetic mean concentrations of the Phase 1, SL029, and SL012 sample sets are all consistent with that of the original Transect samples (although the SL029 and SL012 sample distributions appear to be different, the former having lower arithmetic average concentration than the latter, but a larger spread of concentrations). The area around SL015 appears to be a "hot spot," with somewhat higher mean concentration in that vicinity.

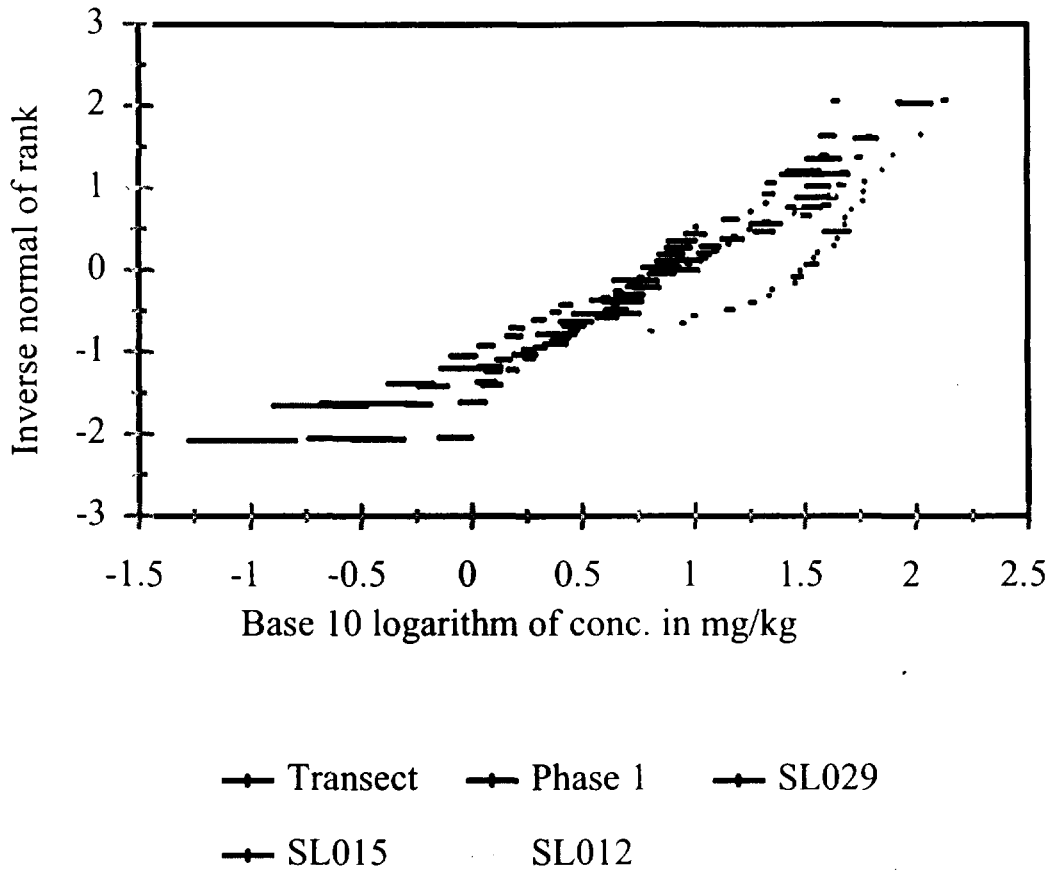

Figure U.1 Distributions of surface soil concentrations in various sample sets

U.2.3 Hunter/fisher scenario

The wide-area Phase 1 sampling gave an estimate of mean concentration in the former Plainwell impoundment that is practically identical to the former Transect samples (Table U.2). Other local sampling (SL029, SL012, SL015) indicated that there is some variation from place to place within the impoundment, with SL015 results indicating a reasonably large area with average surface soil concentration about double the average over the whole former impoundment. However, for the screening risk assessment of Section 5, what is required for exposure point concentration for the hunter/fisher scenario is the average over the whole former impoundment (as an approximation of the average concentration that a hunter/fisher would be exposed to in many trips to different locations within the former impoundment). Evaluation of this average is best performed by averaging over locations uncorrelated with surface soil concentrations (*e.g.* randomly spread throughout the former impoundment, or on a grid if the surface soil

concentration varies randomly within the former impoundment). Averaging together just the former Transect samples and the more recent Phase 1 samples, which best approximate these ideals, gives the estimates indicated in Table U.3 for the mean and upper confidence limit on the mean (using the standard approach, see Section 5.1).

Table U.3 Statistics for various approaches to estimating exposure point concentration in the Plainwell impoundment.

	Number of samples	Total PCB conc. (mg/kg) [a]			p-value for log-normal [c]	UCL95 estimate [b] (mg/kg)	
		Mean	SD	Max		Normal	Lognorm
Transect	30	17.6	22.2	102	0.46	24.5	**39.9**
Transect + Phase 1	61	17.7	22.0	102	0.19	22.3	**38.9**
All data	152	20.7	23.5	135.3	0.0005	**23.8**	38.6
All data (2 - lognormal model	152	20.7	23.5	135.3	---	---	27.6

[a] Using ½ detection limit for all non-detected Aroclors that were ever detected.
[b] Upper 95th percent confidence limit on the mean, assuming the underlying distribution is normal (Normal) or lognormal (Lognorm). The former uses the t-statistic, the latter the procedure of Land (1971, 1973, 1974, 1975, 1988; Lyon & Land, 1999). **Bold** figures indicate the estimate that should be selected using the typical approach.
[c] Shapiro-Wilk statistic (Royston, 1982, 1993, 1995) for the logarithms of the sample values.

Including all the available samples, including those sampled on local grids (SL029, SL015, SL012) might bias the estimate by oversampling concentrations that are too high or too low. In this case, however, the bias is likely to be upward, since two of the sets of samples have means above the mean of the Transect or Transect + Phase 1 data. Table U.3 also shows statistics using standard approaches when incorporating all the available surface soil samples and treating all non-detects as ½ the detection limit. However, in this case neither a normal nor a lognormal assumption is justified for the distribution, so neither of the two standard estimates for upper confidence limit on the mean can be considered very good. A probability plot of all the data (Figure U.2) suggests a two-lognormal model (see Section 5.1) for the distribution, and Table U.3 shows also the upper confidence limit estimate on the mean using this approach (taking account of the range of possible results for non-detects).

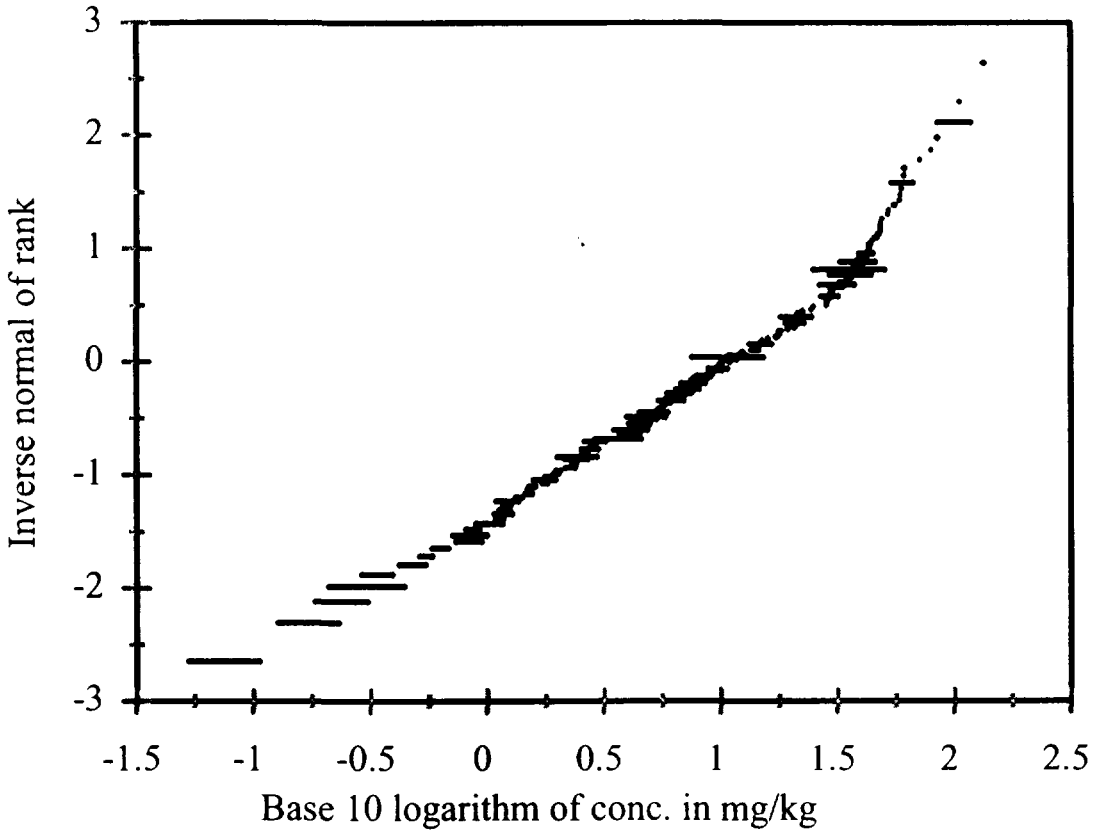

Figure U.2 Distribution of all measured soil concentrations in the former Plainwell impoundment.

All the upper confidence limit estimates for exposure point concentration in the former Plainwell impoundment that take account of the recent data are as low as or lower than (but not substantially lower than) the estimates previously made in the screening risk assessment. The preferred estimate of exposure point concentration for the former Plainwell impoundment was 36.0 mg/kg, obtained as an approximate 95th percentile upper confidence limit using a lognormal model that took account of the range of possible values for non-detects (Section 5.1). The corresponding 2-lognormal model applied to all the available data gives a preferred estimate for exposure point concentration of 27.6 mg/kg, again corresponding to an approximate upper 95th percentile upper confidence limit. The conclusions of that screening risk assessment are thus not altered in any essential detail — the estimated dose rate during exposure for the former Plainwell impoundment is lowered from 0.0024 to 0.0019 μg/kg-day, and the lifetime risk estimate is lowered from 2.8×10^{-6} to 2.1×10^{-6}.

U.2.4 Other soil samples

As already mentioned in Section U.2.2, four samples were excluded from the analysis as being outside the former Plainwell impoundment. These samples all had low PCB concentrations, lower than the 2 mg/kg or 2.5 mg/kg (MIDEQ, 2000 and 2002) considered sufficiently protective in the majority of the floodplain.

Grid 4 around location SL053 in reach 2 of the river is outside the area of the former Plainwell impoundment, and the soil samples from this grid generally had very low concentrations of PCBs. Only 4 of the 32 soil samples had detectable PCB levels, and in all cases the total PCB concentrations (non-detects counted as ½ the detection limit) were below 0.55 mg/kg.

The radial grids sampled in Phase 2 around the other four chosen Phase 1 locations (SD045, SD036, SD030, SD004) primarily sampled locations below standing water — only 15 of the surface samples, all from SD030 (in reach 2), were not below standing water. Those soil samples had an average PCB concentration of 3.2 mg/kg (maximum 8.5 mg/kg, non-detects treated as ½ detection limit).

U.3 Health risk estimates from modeled exposures to fish, using fixed toxicity estimates

U.3.1 Variability of doses across the population

Incorporating the analyses described in Section 6 of our June 1, 2001 report, and setting all the uncertainty distributions at central tendency estimates (either maximum likelihood estimates (MLE) or means), the variability distribution for lifetime average dose rate of total PCBs is given in Figure U.3.[4] This curve describes the variation in lifetime average dose rates among a population of fish-eaters who start eating fish in 1999. The effect of later starting years is simply to multiply this distribution by the factor 0.953 per year, due to the exponential decay of the concentrations in fish — a continuation into the future of the trend observed in concentrations of PCBs in fish over the last 10–20 years.

The median estimate for lifetime average dose rate (50% of the population would have higher dose rate, 50% lower) is 0.0025 µg/kg-day, while approximately 93% of such a fish-eating population would have a lifetime average dose rate of 0.05 µg/kg-day or less, corresponding to a lifetime risk estimate of approximately 1×10^{-4}. Table U.4 summarizes other values at the upper end of the distribution, and illustrates the corresponding hazard indexes and lifetime risk

[4] This distribution was obtained from 1,000,000 Monte Carlo iterations. See spreadsheet Dose_life_results.wb3, Appendix B.21. Percentiles other than those listed in the text or tables can be read from this spreadsheet.

estimates when computed using the MESB HPV of 0.05 µg/kg-day as the reference dose for the hazard index calculation, and the EPA upper bound potency estimate of 2 kg-day/mg.

Table U.4 Upper variability percentiles of dose, hazard index, and risk, at the MLE for uncertainty

Variability Percentile	Lifetime average dose rate, µg/kg-day	Hazard index ‡	Lifetime risk estimate ‡
50.0%	0.0025	0.05	5e-06
90.0%	0.035	0.7	7e-05
92.7%	0.05	1.0	1e-04
95.0%	0.071	1.4	1e-04
99.0%	0.24	4.9	5e-04
99.9%	0.85	17	2e-03

‡ Using the MESB HPV of 0.05 µg/kg-day as a reference dose, and the EPA upper bound potency estimate of 2 kg-d/mg.

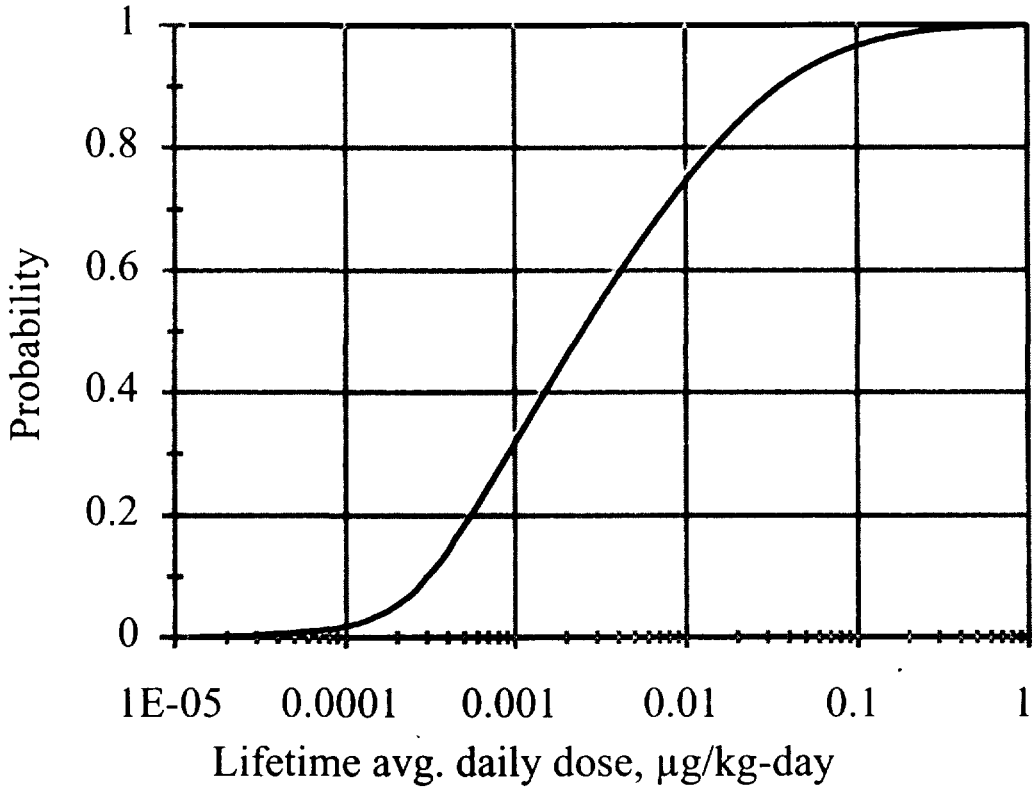

Figure U.3 Population variability in lifetime average daily dose, µg/kg-day, with maximum likelihood estimates for uncertainty

The variability distribution for lifetime average daily dose is approximately lognormal[5] (the parameters of the best fitting lognormal are a median of 0.0029 µg/kg-day and a geometric standard deviation of a factor of approximately 6.35). This distribution describes the differences among the population due to the differing habits of each individual — such as the differences in numbers of meals of fish eaten per year, the length of time for which they eat fish during a lifetime, and so forth. In principle, it would be possible to identify where any particular individual lies on this variability distribution by finding out for that individual how much fish he

[5] This is to be expected from the structure of the model, even though not one of the variability distributions or uncertainty distributions included in the calculations is lognormal.

eats, for how long he eats fish from the Kalamazoo during his lifetime,[6] how large are his meals of fish, which fish species he eats, and where he catches them.

The distribution of dose rates averaged over the periods during their life that people actually eat fish from the Kalamazoo is shown in Figure U.4 (again, this is for uncertainties set at central estimates — MLEs or means).[7] These dose rates are higher than the lifetime averages shown in Figure U.3, because most people do not eat fish from the Kalamazoo for their whole lives. During the time they eat fish from the Kalamazoo, approximately 51% of the fish-eating population would have dose rates below the 0.05 μg/kg-day MESB HPV (Fischer *et al.*, 1998), while the 90th, 95th, 99th, and 99.9th percentiles are at 0.27, 0.45, 1.22, and 3.44 μg/kg-day respectively, corresponding to hazard indexes of 5, 9, 24, and 69 if the MESB HPV is used as a reference value. However, these dose rates occur over periods ranging from 1 year to a lifetime, so that comparison with any single long-term-average safe dose rate is problematic (see Section 4.3.5). Moreover, it should be noted that individuals high on the distribution shown in Figure U.4 may be substantially lower on the distribution shown in Figure U.3, because of the differences between people in the periods for which they eat fish.

[6] This requirement to know for how long during a lifetime the individual eats fish from the Kalamazoo indicates that it would only be possible to identify the location on the variability distribution for any individual at the end of his lifetime.

[7] See spreadsheet Dose_while_results.wb3, Appendix B.22. Percentiles other than those listed in the text and tables can be read from this spreadsheet.

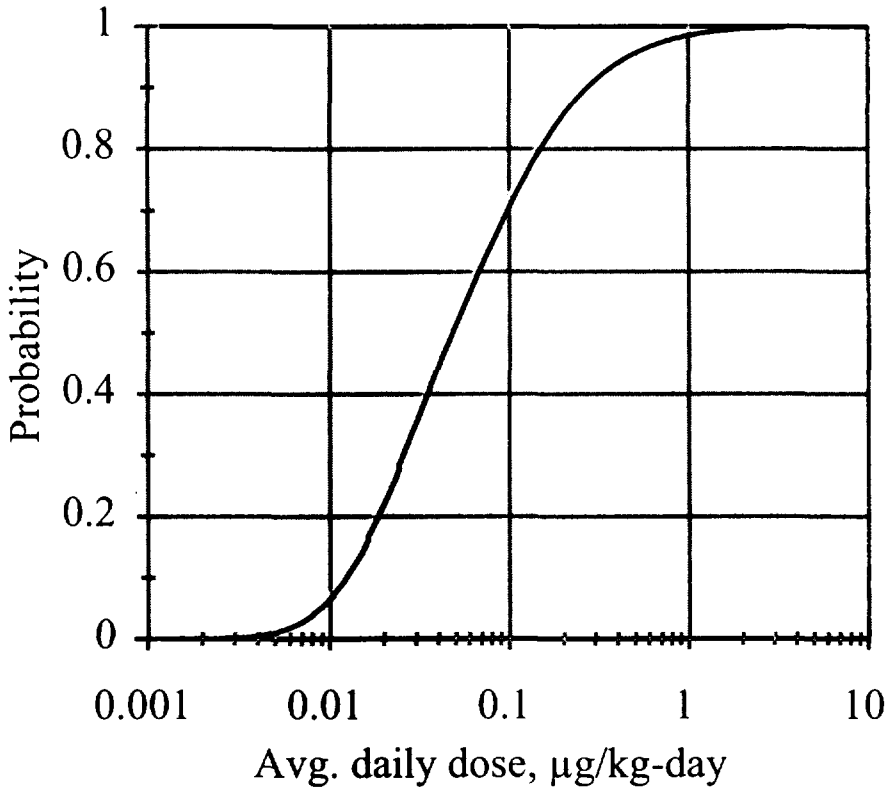

Figure U.4 Population variability of the average dose rate (µg/kg-day) during the period of their lives that people actually eat fish from the Kalamazoo.

U.3.2 Uncertainties of the variability distribution

In addition to the variation in dose rates from individual to individual, there are uncertainties about the average dose rate for any individual. The uncertainties incorporated in the modeling have been described in individual sections above, and from them we have estimated the uncertainties associated with the variability distributions.

Incorporating all the identified uncertainties leads to uncertainty distributions for the variability distribution for doses described in Section U.3.1. Figure U.5 shows the distribution of uncertainties for the 50th, 75th, 90th, 95th and 99th percentiles of the variability distribution for

lifetime average dose rate.[8] For all the variability percentiles, the uncertainty distribution is fairly well represented by a lognormal with a geometric standard deviation of approximately 1.43. The horizontal line in Figure U.5 shows the location of the MLE estimate for the variability distribution on these uncertainty distributions — the MLE estimate is at about the 25th to 40th percentile of the uncertainty distribution.[9]

An alternative presentation of the same information is given in Figures U.6 and U.7 which both show, on slightly different scales, the full variability distribution for lifetime average dose together with its uncertainty. Figure U.6 shows the MLE variability distribution (solid line on the left), together with (moving to the right) the 50th, 75th and 95th percentiles of uncertainty distributions about the variability distribution. Figure U.7 shows the same, but with an inverse normal scale on the left — the straightness of the curves illustrates how close to lognormal is the variability distribution.

Table U.5 summarizes estimates of lifetime average dose rate, lifetime risk and hazard index for the upper 90th percentile of the uncertainty distribution on the 50th, 90th, 95th, and 99th percentiles of the variability distribution.

Table U.5 Doses, hazard indexes, and risk estimates, at the upper 90th uncertainty percentile for upper end variability percentiles

Variability Percentile	MLE	Upper 90th uncertainty percentile		
	Lifetime average dose rate µg/kg-day	Lifetime average dose rate, µg/kg-day	Hazard index ‡	Lifetime risk ‡
50%	0.0025	0.0046	0.1	9e-06
90%	0.035	0.062	1.2	1e-04
95%	0.071	0.12	2.5	2e-04
99%	0.24	0.44	8.7	9e-04

‡ Using the MESB HPV of 0.05 µg/kg-day as a reference dose, and the EPA upper bound potency estimate of 2 kg-d/mg.

[8] See spreadsheet Dose_life_results.wb3, Appendix B.21. Results for uncertainty and variability percentiles other than shown on the figures and listed in the tables can be read from the spreadsheet, and graphs of them constructed in the spreadsheet.

[9] The jaggedness of the horizontal line is largely an artefact. The Monte Carlo simulation was performed using 50,000 iterations for the variability distributions, repeated 5,000 times with different samples to obtain the uncertainty distributions. The position of the MLE was evaluated only to the nearest 1% in positioning this line.

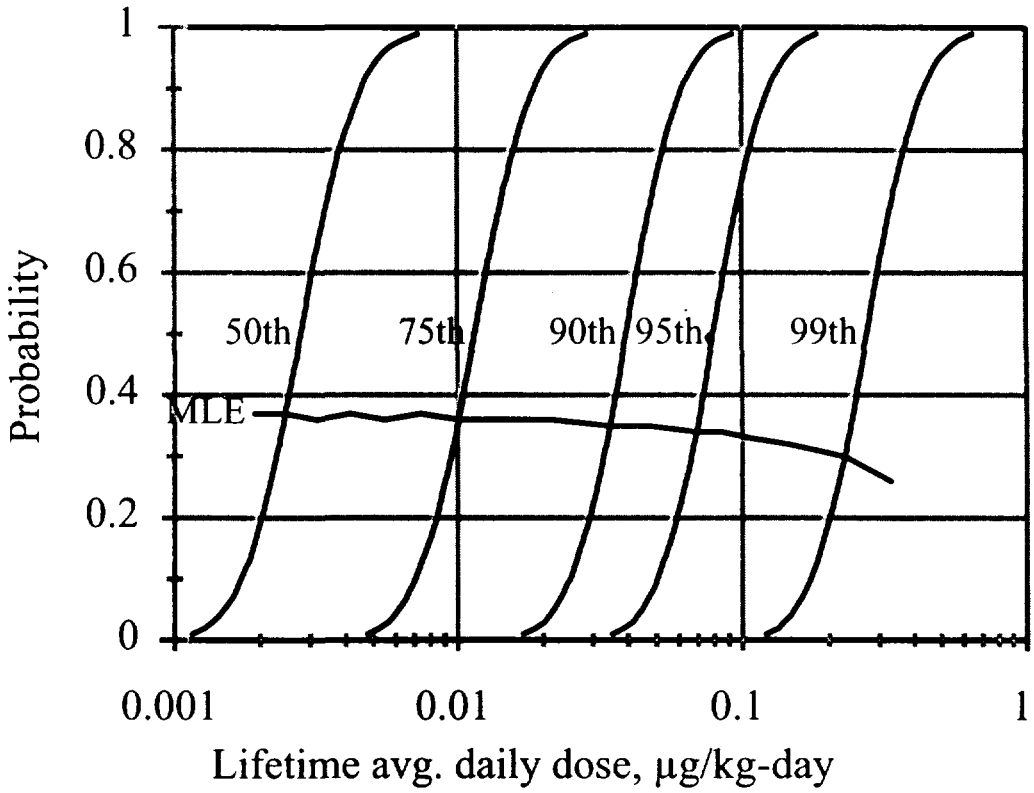

Figure U.5 Uncertainty distributions for various percentiles of the variability distribution for lifetime average dose rate.

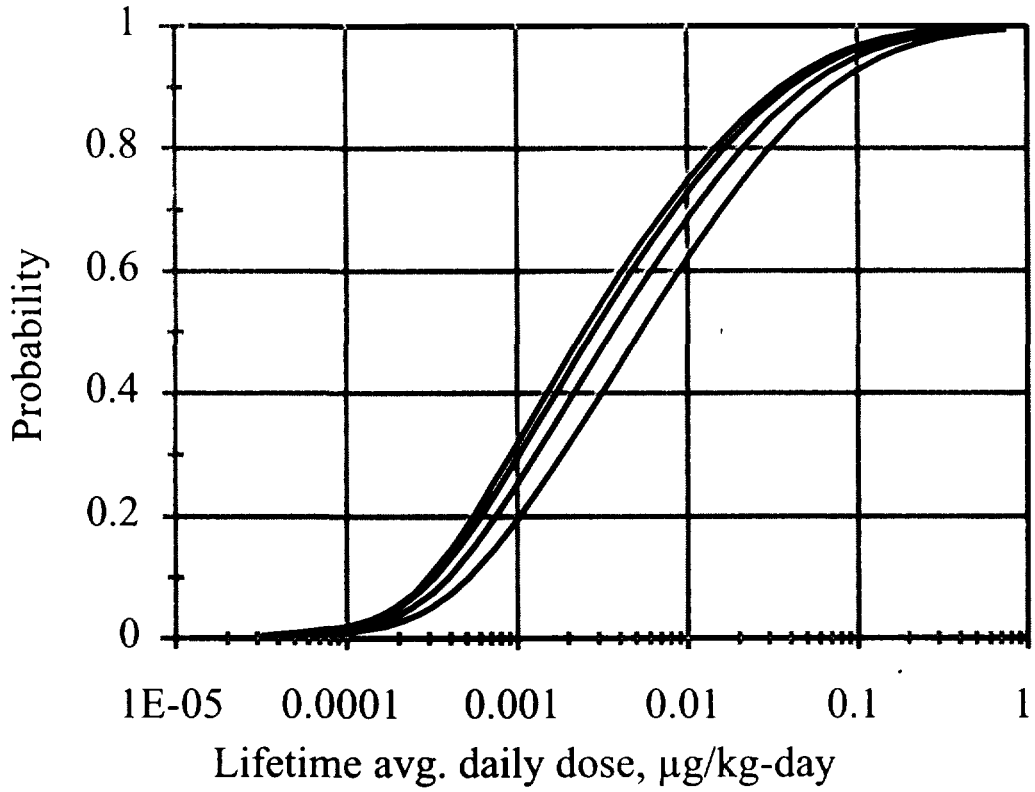

Figure U.6 MLE variability distribution for lifetime average dose rate (to the left), and 50th, 75th and 95th percentiles (moving to the right) in uncertainty for this variability distribution.

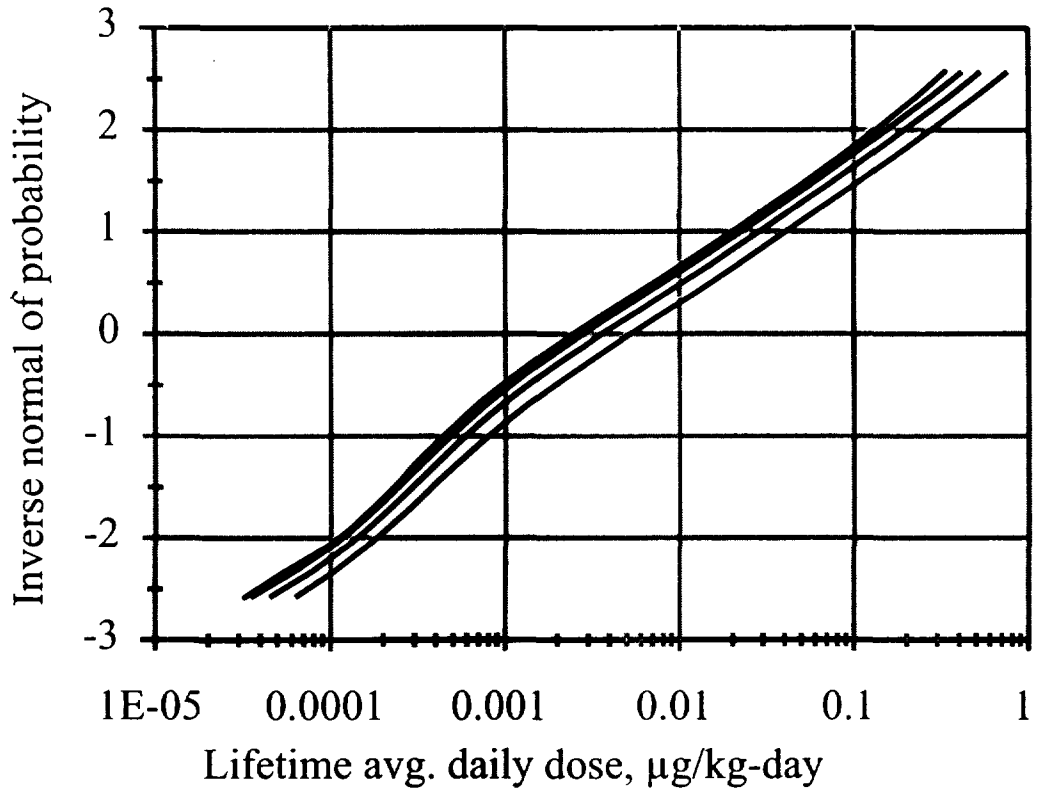

Figure U.7 MLE variability distribution for lifetime average dose rate (to the left), and 50th, 75th, and 95th percentiles (moving to the right) in uncertainty for this variability distribution (alternate scale).

The same type of analysis may be performed for the dose during exposure.[10] Figure U.8 shows the distribution of uncertainties for the 50th, 75th, 90th, 95th, and 99th percentiles of the variability distribution for average dose rate during exposure. For all the variability percentiles, the uncertainty distribution is fairly well represented by a lognormal with a geometric standard deviation of approximately 1.34. As before, the horizontal line in Figure U.8 shows the location of the MLE estimate for the variability distribution on these uncertainty distributions — the MLE estimate is again at about the 25th to 40th percentile of the uncertainty distribution.

[10] See spreadsheet Dose_while_results.wb3, Appendix B.22.

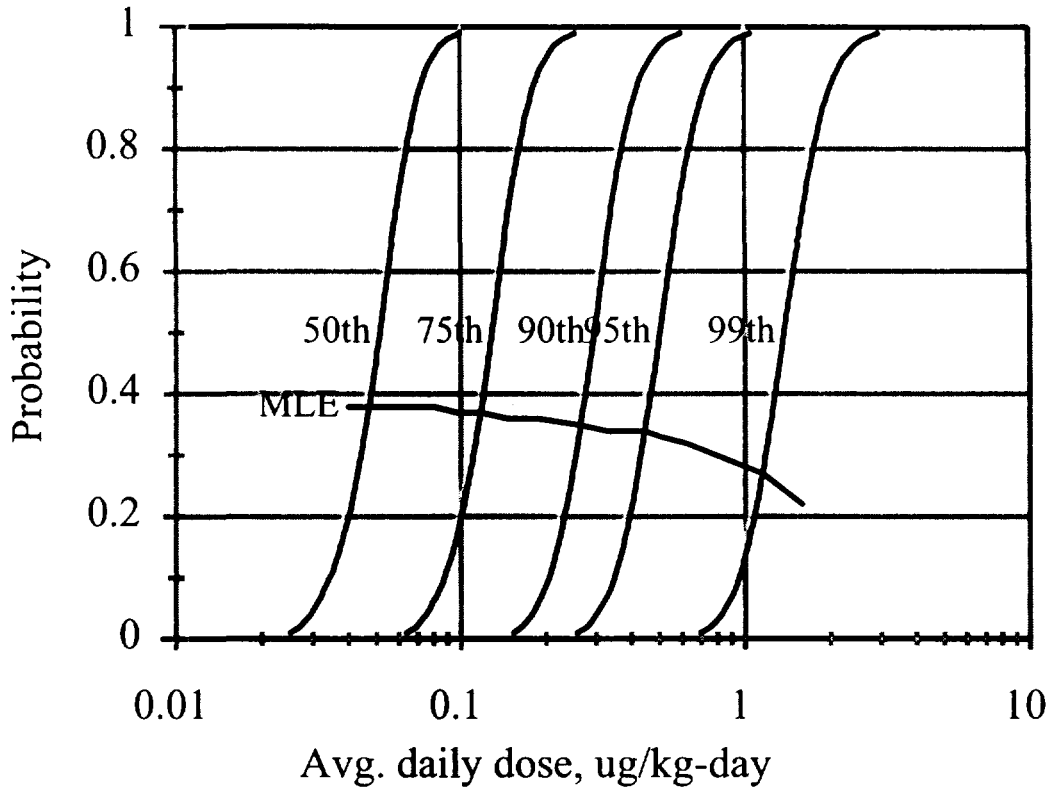

Figure U.8 Uncertainty distributions for various variability percentiles of the dose during exposure.

For the 90th percentile of the variability distribution for dose during exposure (MLE value 0.27 μg/kg-day), the upper 90th percentile of the uncertainty distribution is at 0.42 μg/kg-day. For the 95th percentile on the variability distribution (MLE estimate 0.45 μg/kg-day), the upper 90th percentile of the uncertainty distribution is 0.72 μg/kg-day. For the 99th percentile on the variability distribution (MLE estimate 1.22 μg/kg-day), the upper 90th percentile of the uncertainty distribution is 1.98 μg/kg-day. Once again, however, comparison of these values with any single safe dose rate is problematic, as discussed in Section 4.3.5, since they occur over widely varying periods of exposure.

U.3.3 Combined variability and uncertainty — the random individual

For a randomly chosen individual, about whose habits we know nothing except that he eats fish from the Kalamazoo, there is no distinction between variability and uncertainty — the selection of the individual at random makes the variability equivalent to uncertainty. For such a randomly chosen individual, the uncertainty distribution for lifetime average dose rate may be obtained from the modeling by treating variability and uncertainty equivalently. This is the usual situation for uncertainty modeling, and corresponds to the practice in most risk assessments (including the HHRA) of choosing values from the various variability and uncertainty distributions without regard to whether they reflect variability or uncertainty. Performing this evaluation leads to the combined distribution for lifetime average dose shown in Figure U.9.[11] This is almost indistinguishable from the variability distribution shown in Figure U.3, because the uncertainty is so much less than the variability. Table U.6 shows the upper percentiles of the combined uncertainty and variability distribution for lifetime average dose, together with the corresponding hazard indexes and lifetime risk estimates. The combined distribution is well approximated by a lognormal (with parameters of: median 0.0032 μg/kg-day, geometric standard deviation a factor of 6.77).

Table U.6 Upper variability percentiles of dose, hazard index, and risk, for the combined variability and uncertainty distribution

Variability Percentile	Lifetime average dose rate, μg/kg-day	Hazard index ‡	Lifetime risk estimate ‡
90.0%	0.041	0.8	8e-05
91.5%	0.05	1.0	1e-04
95.0%	0.084	1.7	2e-04
99.0%	0.30	5.9	6e-04
99.9%	1.09	22	2e-03

‡ Using the MESB HPV of 0.05 μg/kg-day as a reference dose, and the EPA upper bound potency estimate of 2 kg-d/mg

[11] See spreadsheet Dose_life_results.wb3, Appendix B.21. Doses at other percentiles may be read from the spreadsheet.

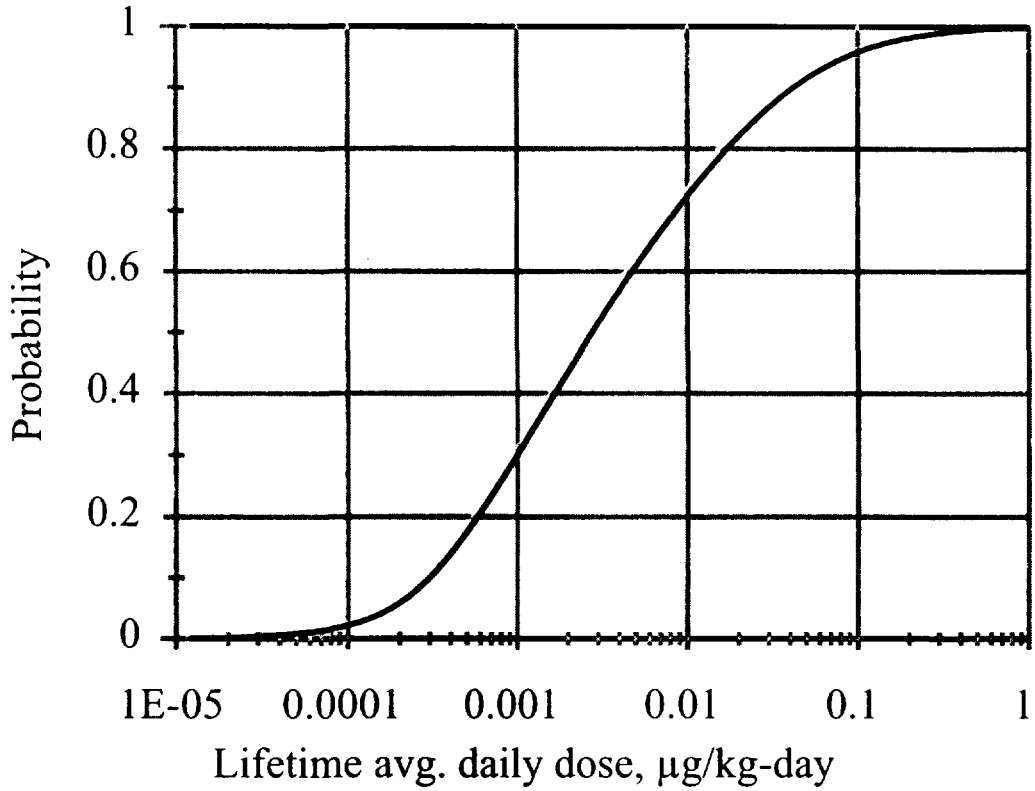

Figure U.9 Combined variability and uncertainty for lifetime average dose rate — the uncertainty distribution for a randomly picked individual.

There is a similarly small effect of uncertainties on the estimates of dose rate during exposure (so that the graph, Figure U.10, is almost indistinguishable from Figure U.4) — again the variability is much larger than the uncertainty.[12] Approximately 49% of people randomly selected from the fish-eating population would have dose rates below the 0.05 µg/kg-day that was endorsed as safe for long-term exposure by the Michigan Environmental Science Board (Fischer *et al.*, 1998), while the 90th, 95th, 99th, and 99.9th percentiles are at 0.31, 0.53, 1.5, and 4.5 µg/kg-day respectively. Once again, these average doses occur over periods ranging from one year to a lifetime, so that comparison with any single acceptable level is problematic (see Section 4.3.5).

[12] See spreadsheet Dose_while_results.wb3, Appendix B.22. Doses at other percentiles may be read from the spreadsheet.

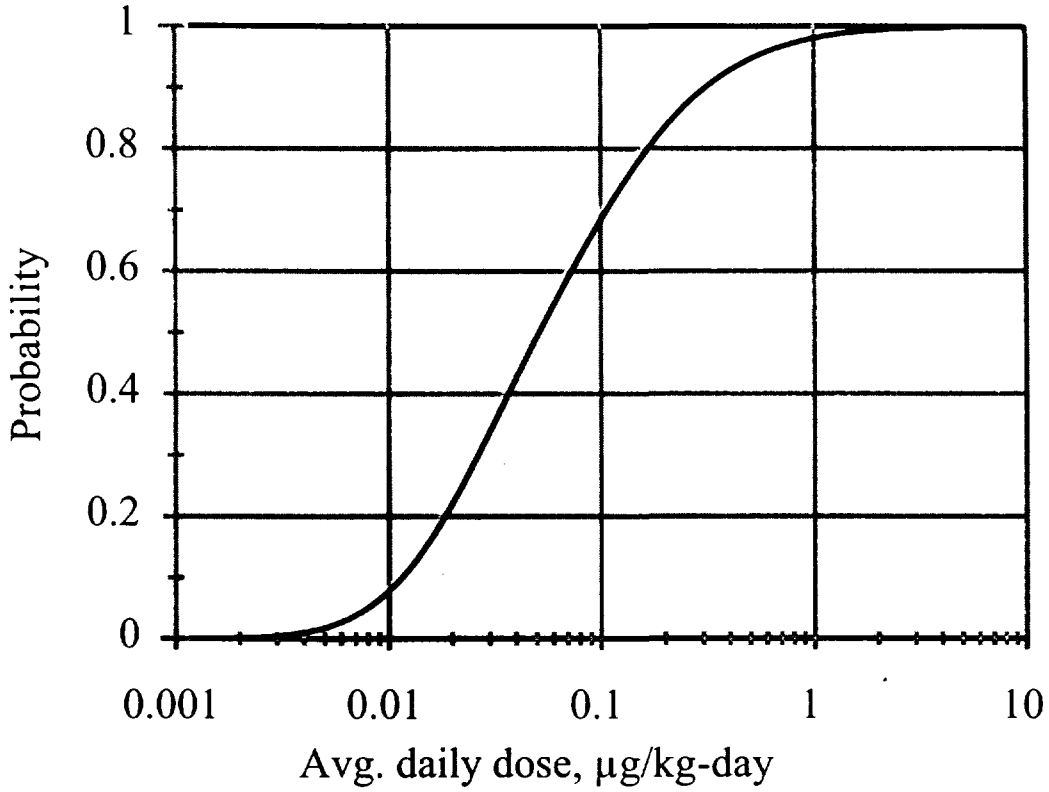

Figure U.10 Combined variability and uncertainty for average dose rate during exposure — the uncertainty distribution for a randomly picked individual.

With the fixed toxicity estimates used in this update, the distribution of lifetime risk estimates for a random individual may be obtained directly from Figure U.9 by multiplying the doses by the EPA potency of 2 kg-d/mg. Similarly hazard indexes may be obtained by dividing the doses by the MESB HPV of 0.05 µg/kg-day. The distribution for lifetime risk is shown in Figure U.11, and that for hazard index in Figure U.12. The hazard index distribution has been computed using the estimates of lifetime average dose rate, corresponding to the long term average dose rate implied in the MESB HPV.

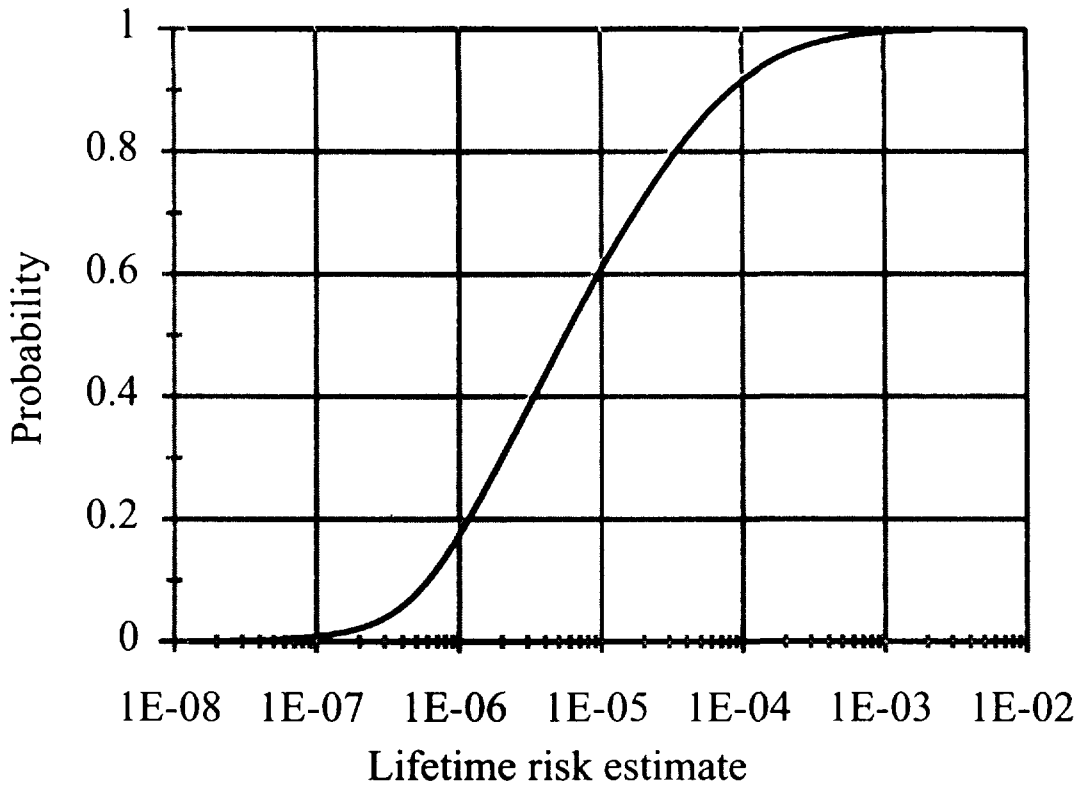

Figure U.11 Uncertainty distribution of lifetime risk estimate for a random individual (EPA upper bound potency estimate)

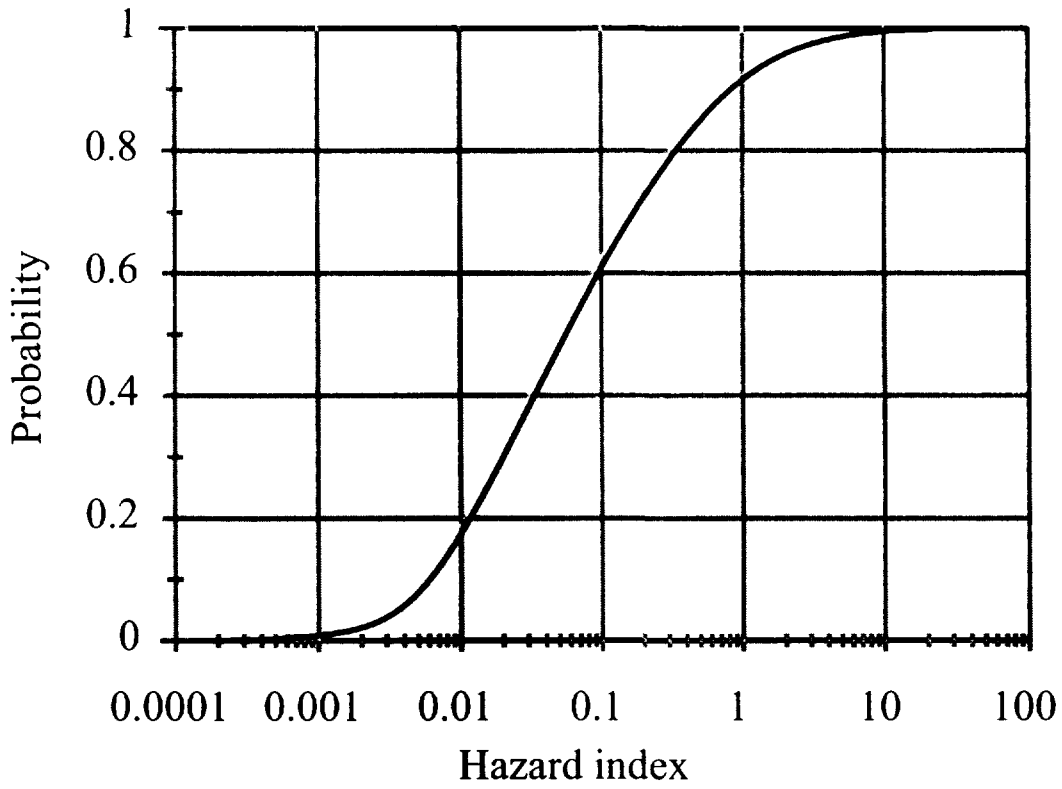

Figure U.12 Uncertainty distribution of hazard index for a random individual (using MESB HPV as reference value, and lifetime average dose rate).

To illustrate the combinations of circumstances that lead to a lifetime risk estimate of 1.0×10^{-4} and hazard index of 1.0, at the 91.5 th percentile of the uncertainty distribution for the random individual, Table U.7 shows a selection of ten equally likely possibilities (these were taken from the Monte Carlo simulation; they are from the ten simulations giving risk estimates closest to 1.0×10^{-4}). The average PCB concentration listed in Table U.7 is an average of the PCB concentrations in different fish species, weighted by the fraction of meals of those species, and averaged over the period of exposure. Table U.8 shows the corresponding 10 combinations of average PCB concentrations in 1999 for the individual fish species, and the fractions of meals of each of those species. The concentrations shown in Table U.7 may be obtained from Table U.8 by weighting the fish concentrations by the meal fractions, and then accounting for the decline with time of the PCB concentration — see Equations 6.1 and 6.7 (see spreadsheet

Examples.wb3, Appendix B.20, for a detailed calculation check of all the examples given in this section, and others).

Table U.7 Examples of combinations of circumstances that result in a risk estimate of 1.0×10^{-4}. (see spreadsheet Examples.wb3, Appendix B.20)

Initial age (years)	Duration eating fish (years)	Effective additional duration (years)	Fish meals per year	Average weight of a meal (kg) [a]	PCB survival during cooking	PCB conc. decrease per year [b]	Average PCB conc. (mg/kg)
5.4	34.4	6.6	12.3	0.34	0.818	0.0468	0.64
14.1	30.3	4.3	24.3	0.23	0.804	0.0491	0.58
30.7	15.0	0.9	107.6	0.11	0.561	0.0561	0.82
40.1	29.9	-8.3	53.9	0.34	0.512	0.0388	0.44
28.4	23.0	0.8	63.3	0.11	1.000	0.0544	0.52
29.8	29.4	-1.1	68.4	0.11	0.653	0.0382	0.63
20.6	3.0	0.6	39.9	0.34	0.753	0.0259	2.43
12.0	4.0	1.0	134.5	0.23	0.969	0.0644	0.61
10.4	3.0	0.8	80.3	0.23	0.549	0.0365	2.35
17.1	14.8	2.8	18.1	0.34	0.843	0.0504	0.98

[a] The fish meal weights in this column correspond to those in Table 6.13. For example, 0.34 kg = 12 oz, 0.23 kg = 8 oz.
[b] The decrease per year in the natural logarithm of the concentration.

Tables U.7 and U.8 show combinations of circumstances corresponding to a lifetime risk of 1.0×10^{-4} and hazard index of 1.0. It is apparent that a wide range of combinations of circumstances can lead to the same estimates of risk — it is impossible to focus on just one or two circumstances as being the major contributors.

Table U.8 Fraction of meals of each species of fish, together with average concentration in those fish in 1999, for the ten examples in Table U.7. Each entry shows the fraction of meals above the concentration in mg/kg (see spreadsheet Examples.wb3, Appendix B.20).

Walleye	Sucker	Carp	Bass	Pike	Panfish	Catfish	Turtle
0.063	0.015	0.018	0.096	0.012	0.086	0.706	0.005
1.017	0.613	1.446	1.488	1.868	0.482	1.375	0.495
0.044	0.010	0.032	0.149	0.036	0.164	0.534	0.031
0.749	0.654	4.234	1.144	1.873	0.488	1.146	0.593
0.060	0.002	0.007	0.181	0.007	0.038	0.548	0.157
1.262	1.512	2.433	1.250	2.782	0.472	1.145	1.443
0.033	0.000	0.000	0.100	0.033	0.667	0.133	0.033
0.825	0.782	4.944	1.179	1.666	0.483	1.477	0.820
0.016	0.004	0.012	0.050	0.011	0.540	0.316	0.051
1.186	1.486	8.873	1.084	1.823	0.324	1.621	0.533
0.000	0.000	0.000	0.333	0.000	0.333	0.333	0.000
0.635	0.716	4.335	1.447	2.098	0.347	1.327	0.875
0.093	0.000	0.465	0.140	0.116	0.070	0.070	0.047
1.388	0.817	3.939	1.183	1.970	0.511	1.289	1.026
0.006	0.001	0.004	0.019	0.004	0.750	0.211	0.004
0.850	1.644	2.269	1.028	4.063	0.399	1.579	0.827
0.000	0.000	0.167	0.250	0.250	0.250	0.017	0.067
0.760	1.474	7.409	0.938	3.313	0.470	0.984	0.763
0.126	0.030	0.037	0.191	0.023	0.173	0.411	0.009
0.673	1.742	1.905	1.147	1.759	0.358	2.065	1.017

U.3.4 Population effect

Evaluation of a total population effect requires accounting for the differences among the individual members of the population. The Monte Carlo approach we have taken allows us to do this by averaging over the variability distribution to obtain the population average for lifetime average dose, allowing estimation of the total population effect and its uncertainty distribution, as explained in Section 6.8. Averaging over uncertainties, the mean value for lifetime average dose in the population of those eating fish is 0.021 μg/kg-day, corresponding to a lifetime risk estimate of approximately 4.1×10^{-5} (using the U.S. EPA upper-bound potency estimate of 2 kg-day/mg) for those entering the population in 1999 (the index year for these calculations). The

full uncertainty distribution for population lifetime risk for those entering the population of Kalamazoo fish eaters in 1999 is given in Figure U.13.[13]

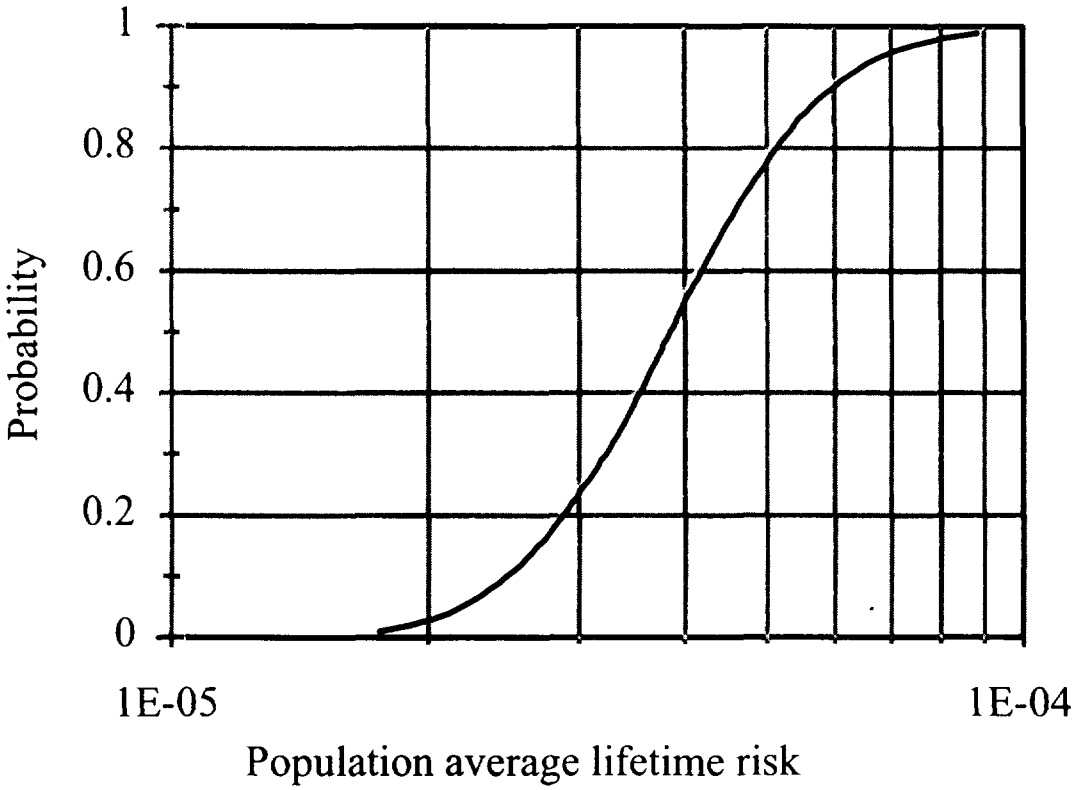

Figure U.13 Uncertainty distribution for population average lifetime risk (EPA upper bound cancer potency estimate)

This distribution strictly applies to the population of anglers on the Kalamazoo who eat the fish they catch, although it is likely to overestimate the risks for the total population described in Section 6.7 who eat fish from the Kalamazoo River (including the anglers, their families, and others to whom they give fish), and to whom we apply the risk estimates. This latter total population number is on the order of 6,870 persons actively eating fish at any one time (see Section 6.7). The turnover rate is about 15% of that population per year (see Section 6.4), or about 1,004 persons/year who enter the total population of ever-eaters of Kalamazoo fish. It

[13] See spreadsheet Dose_life_results.wb3, Appendix B.21.

follows that the population of ever-eaters that is alive at any one time is about 70,300 persons (1,004 persons/yr × 70 yr lifetime) although there is considerable uncertainty in this number.

Using the approach of Section 6.8 to take account of the uncertainties in all quantities involved, the median estimate for the long-term-average annual population effect of PCB contamination in fish from the Kalamazoo is about 0.038 cancers per year among ever-eaters (based on those starting to eat the fish in 1999), using the U.S. EPA upper-bound potency estimate of 2 kg-day/mg. The expected number of cancers per year (the average over the uncertainty distribution) is 0.041, and the upper 90th percentile is 0.064. These estimates may be compared with a background cancer rate from all causes (omitting non-melanoma skin cancers) of about 400 per year in the population of about 70,300 ever-eaters of Kalamazoo fish.

The estimates of effect would decrease by about 5% per year as the PCB concentrations decrease. Then adding up all the cancers that might occur due to the PCBs among all the people who ever eat fish from the Kalamazoo at any time from 1999 onwards leads to a total of about 0.79 total cancers (median estimate — the mean and 90th percentile estimates are 1.0 and 1.7 respectively). Since these estimates incorporate the EPA upper bound estimate of carcinogenic potency, they must be interpreted as upper bound estimates with respect to the (omitted) uncertainty in the cancer potency of PCBs. The uncertainty distribution for this upper bound on total number of cancers ever is shown in Figure U.14. Any such cancers would be spread over the lifetimes of the total population who start to eat fish from the Kalamazoo at any time in the future. For some comparison, in the first 50 years (up to 2049), the expected number of background cancers from all causes (except non-melanoma skin cancers) is around 20,000 in the same population.

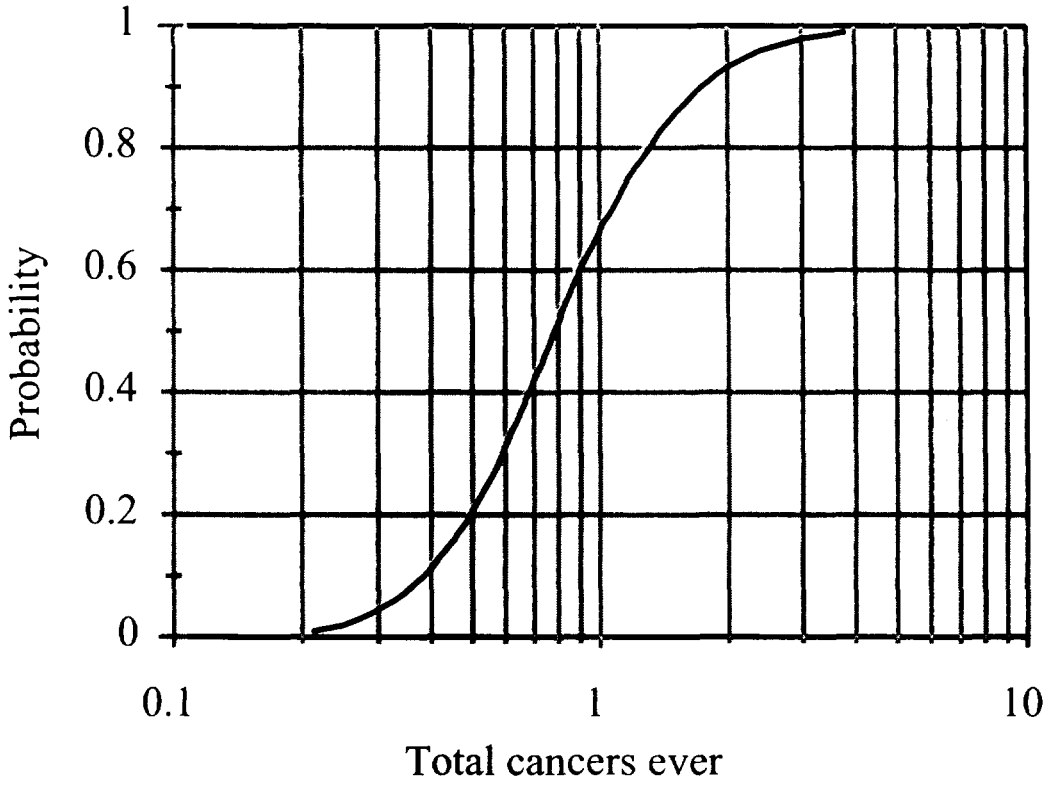

Figure U.14 Uncertainty distribution for upper bound total number of cancers ever (using the EPA upper bound potency estimate).

U.4 Additional references for the Update

Note: References are included here only if they are not already in the reference list at Section 9 of our June 1, 2001 report.

USACE (2001). U.S. Army Corps of Engineers Corpscon software version 5.11.08 Geodetic Applications Division U.S. Army Topographic Engineering Center, Alexandria, Virginia 22315-3864. Available at http://crunch.tec.army.mil/software/corpscon/corpscon.html, at July 18, 2002.

MiDEQ (2002). *Final (Revised) Human Health Risk Assessment Allied Paper, Inc./Portage Creek/Kalamazoo River Superfund Site.* Michigan Department of Environmental Quality Environmental Response Division. January, 2002.

Owen, A.B. (2001). *Empirical Likelihood.* Monographs on Statistics and Applied Probability. Chapman and Hall/CRC Press. ISBN 1584880716.

USGS (1973). U.S. Geological Survey, U.S. Department of Interior, Denver, CO; Reston VA. 7.5 minute map: Otsego, Michigan quadrangle; map: 42085-D6-TF-024.

Weston (2002). Roy F. Weston Inc. *Removal Assessment Report for Allied Paper – Kalamazoo River Site Otsego/Plainwell, Michigan.* February, 2002.

U.5 Appendix to the Update: Spreadsheet details

This section is an update to Appendix B of our June 1, 2001 report, and summarizes the information and calculations performed in additional spreadsheets now included with the electronic addendum (in the subdirectory Finaldata). The spreadsheets added are:

Stage1.csv
Stage2.csv
Stage1_fin.wb3
Stage2_fin.wb3
Plainwell.wb3

The spreadsheets dose_life_results.wb3, dose_while_results.wb3, and examples.wb3 have been changed, but only to add additional tables and names within them, allowing electronic cross-referencing of extant material — no values or calculations have been altered. Phase_1.wb3 has been slightly augmented to include an estimate of the total number of background cancers expected within a given time horizon. The file Age_structure.wb3 has a slightly later date, but is otherwise unchanged.

U.5.1 Stage1.csv and Stage2.csv

These contain the raw data, as received through BBL from U.S. EPA. The operations performed on these files to allow subsequent analysis are as follows:

STAGE 1 samples

Open Stage1.csv in Excel.

Copy the whole sheet to Stage1_fin.wb3, sheet Orig_data.

Sort on sys_loc_code and examine only those with code beginning SL. These samples are surface soil samples — others with code beginning SD are sediment samples from below standing water; this identification overrides the sample_matrix_code (personal communication with D. Profusek, BBL, July 2002).

Sort on start_depth and examine only surface samples — those with start_depth equal to 0.

Sort on result_unit and examine only those with result_unit equal to UG/KG (this eliminates the results measuring TOC [%] and PCDD/PCDFs [NG/KG]).

Sort on reportable_result, and examine only those with value Yes (laboratory selected results).

Sort on sys_loc_code, sample_type_code, and chemical_name to put all individual locations together, with chemical analyses in standard order, and with FD samples separated from N samples. FD was interpreted as "field duplicate" for this analysis.

Search for and remove all spaces in the Detect_flag column (to allow error trapping if the symbol is not "Y" and "N")

STAGE 2 samples

Open Stage2.csv in Excel.

Sort on start_depth to select only those remaining samples with start_depth equal to 0 (surface samples).

Sort on reportable_result and select only the remaining samples with reportable_result=YES.

Sort on sys_loc_code, sample_type_code, and chemical_name to put all individual locations together, with chemical analyses in standard order, and with FD samples separated from N samples. For some samples (SL029-2, SL029-14, SL029-16, SL029-18, SL029-21) FD and N samples had been mixed by the laboratory in producing a complete set of reportable results for all Aroclors. These mixed sets were treated as a single sample, and individually sorted on chemical_name to put the chemical analyses in standard order. In all other cases where FD samples were reported, a complete set of both FD and N samples (one for each Aroclor) were reported. These were treated as duplicates.

The resulting sample set (2193 rows) was copied to sheet Orig_data of Stage2_fin.wb3.

Search for and remove all spaces in the Detect_flag column (to allow error trapping if the symbol is not "Y" and "N").

Subsequent analysis was performed in Quattro Pro spreadsheets.

U.5.2 Stage1_fin.wb3

Sheet Origdata
Columns A..AD contain the original data as imported from Stage1.csv. Columns AH..AM extract the individual measured mass fractions, and compute the totals. Note that the non-detects for Aroclors 1221 and 1232 are omitted (these Aroclors are treated as being not present). Column AO confirms that Aroclor 1221 and 1232 were never detected.

Sheet TotPCB
Columns C..G concatenate total PCB data into a list. Column H records the reach of the river. Columns I..J are not used. Columns K..M locate and combine duplicates. Columns O..U are a re-arrangement to place reaches together, and place together samples in the former Plainwell impoundment (column T). Columns V..W record some counts. Columns X..Z are for plotting locations (chart "Location"). Columns AB..AD record ranges and point estimates of total PCBs for the former Plainwell impoundment.

U.5.3 Stage2_fin.wb3

The sheet names and operations performed are essentially identical to those performed for Stage1_fin.wb3, although the columns are slightly different.

U.5.4 Plainwell.wb3

Sheet A (the only sheet)
Columns A..Q, rows 1..42 are copies of the data for soil samples in the former Plainwell impoundment, copied by value from other spreadsheets as listed. Columns A..M, rows 50+, are used for setting up graphs. No other calculations are performed in this area. Columns Z..AH take the point estimates for all the sample sets and perform standard analyses (see Section B.4). Columns AK..AQ perform F-tests and t-tests on the sample sets and their logarithms. Columns AX..BA fit a 2-lognormal model to SL015 (not used). Columns BE..BI perform an empirical likelihood calculation (Owen, 2001) on SL015 (not used). Columns BJ..BT combine all data and perform a standard analysis. Columns BV..CH evaluate a 2-lognormal model for all the data combined.